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FULWIDER PATTON LLP
HOWARD HUGHES CENTER
6060 CENTER DRIVE, TENTH FLOOR
LOS ANGELES, CA 90045

EXAMINER	
SCHMIDT, EMILY LOUISE	
ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/664,004	BURKETT ET AL.	
	Examiner	Art Unit	
	Emily Schmidt	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *4,5,8,9 and 18-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 6, 7, 10-17, and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1, 3, 6, 10, 11, 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murayama et al. (US 2004/0039309 A1) in view of Tezuka (US 6,251,085 B1).

With regard to claim 1, Murayama et al. teach an intraluminal guide wire, comprising: an elongated wire core having a proximal core section and a distal core section having a distal end (Fig. 7); wherein at least a section of the elongated wire core includes at least one of randomized and non-randomized tactile surface contours (Fig. 7 members 17); and a flexible tubular member disposed over the distal core section (Fig. 7 member 4). Murayama et al. do not disclose an uninterrupted polymer coating with a generally constant outside diameter adhering to and contiguous with the at least one of randomized and non- randomized tactile surface contours for at least a portion of the elongated wire core and having a surface contour that follows the at least one of randomized and non-randomized tactile surface contours in the elongated wire core. However, Tezuka teaches a guide wire with an uneven polymer coating and lubricious layer formed by following the outer surface contours of the guide wire which provides for a reduced contact surface to provide for increased slidability (Col. 2 line 64-Col. 3 line 5, claim 1). It would have been obvious to a person of ordinary skill in the art at the time the invention was

made to provide a coating over the surface contours in the device of Murayama et al. which follow the contours of the guide wire because Tezuka teaches this to allow for a reduced contact surface area and to provide slidability to the guide wire. A coating over the catheter would have a generally constant outer diameter as the surface contours provide for a portion of the catheter with a generally constant outer diameter.

With regard to claims 3, 6, 10, and 11, see member 17 (Fig. 7).

With regard to claim 14, Murayama et al. teaches a guide wire with two different sections (Fig. 7 sections 2 and 3). The two sections are made from different alloys (Pg. 4 [0070]), the distal section (Fig. 7 section 2) is made from a Nickel-Titanium alloy (Pg. 4 [0073]) and the proximal section (Fig. 7 section 3) is made from a stainless steel (Pg. 4 [0071]).

With regard to claim 15, Tezuka teaches the coating to be a fluropolymer (Col. 5 line 30).

3. Claims 2 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murayama et al. (US 2004/0039309 A1) and Tezuka (US 6,251,085 B1) as applied to claim 1 above, and further in view of McMahon (U.S. Patent 6,296,616).

With regard to claim 2, Murayama et al. teach an intraluminal guide wire substantially as claimed. Murayama et al. does not teach the surface contours to have a surface to peak amplitude in a range of about .0002 to .002 inches. However, McMahon teaches a guide wire with a plurality of contact and non-contact regions (Fig. 1 guide wire 10). These peaks have a height of about.01-.1mm which is approximately .0003 - .003in. (Col. 2 lines 59-61) and are used to reduce resistance (Col. 3 lines 1-14). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to create surface contours, in the guide wire of

Murayama et al., with a surface-to-peak amplitude of about .0002 to .002 inches as McMahon substantially discloses such a range to reduce the surface contact between the guide wire and the lumen through which it passes and is effective in reducing resistance. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

With regard to claim 7, Murayama et al. teach an intraluminal guide wire substantially as claimed. Murayama et al. does not disclose the spacing between the contours to range between .05 cm to 2 cm. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to vary the number of contours and thus the spacing of the contours to place it within a range of .05 cm to 2 cm because it would serve as a means to adjust the surface contact area and thus the friction to achieve a desired amount of frictional resistance. Further, McMahon teaches a guide wire with a plurality of contact and non-contact regions (Fig. 1 guide wire 10). The peaks of the contact regions have a spacing of .005 cm to .5 cm (Col. 2 lines 57-58) and are used to reduce resistance (Col. 3 lines 1-14). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to create surface contours, in the guide wire of Murayama et al., with a spacing of about .05 to 2 cm as McMahon discloses an overlapping range to reduce the surface contact between the guide wire and the lumen through which it passes and is effective in reducing resistance. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

4. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murayama et al. (US 2004/0039309 A1) and Tezuka (US 6,251,085 B1) as applied to claim 1 above, and further in view of Richardson et al. (WO 01/36034).

With regards to claims 12 and 13, Murayama et al. teach a coated guide wire substantially as claimed but does not disclose the flexible tubular member disposed over the polymer coating, as in claim 12, or the coating disposed over the flexible tubular member as in claim 13. However, Richardson et al. discloses a coated guide wire with a flexible tubular member (Fig. 1 core member 11, proximal section 12, distal section 13, flexible member 14, coating 19). Richardson et al. teaches the coating can be applied anywhere along the core, thus, the flexible guide member would be over the coating (Pg. 20 lines 3-6) and additionally the coating can be applied over the flexible guide member, thus, the coating is disposed over the flexible guide member (Pg. 20 lines 3-6). This provides a lubricious coating to reduce friction. It would have been obvious to a person of ordinary skill in the art at the time the invention as made to dispose the flexible guide over the polymer coating, or the coating over the flexible guide in the device of Prather because Richardson et al. teaches such coatings to be lubricious and applied in any configuration to a guide wire and further it would have been obvious to a person of ordinary skill in the art at the time the invention was made to vary the placement of the coatings in order to achieve a desired amount of frictional resistance.

5. Claims 16 and 17 rejected under 35 U.S.C. 103(a) as being unpatentable over Murayama et al. (US 2004/0039309 A1) in view of Tezuka (US 6,251,085 B1) and McMahon (U.S. Patent 6,296,616).

With regard to claim 16, Murayama et al. teach an intraluminal guide wire, comprising: an elongated core having a proximal core section and a distal core section including a taper transitioning to a distal end (Fig. 7); wherein an exterior surface of the distal core section includes randomized tactile surface contours as part of the distal core section itself (Fig. 7 members 17); and a flexible tubular member disposed over the distal core section (Fig. 7 member 4). Murayama et al. do not disclose a polymer coating having surface contours which follow the contours of the core. However, Tezuka teaches a guide wire with an uneven polymer coating and lubricious layer formed by following the outer surface contours of the guide wire which provides for a reduced contact surface to provide for increased slidability (Col. 2 line 64-Col. 3 line 5, claim 1). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to provide a coating over the surface contours in the device of Murayama et al. which follow the contours of the guide wire because Tezuka teaches this to allow for a reduced contact surface area and to provide slidability to the guide wire. A coating over the catheter would have a generally constant outer diameter as the surface contours provide for a portion of the catheter with a generally constant outer diameter. Murayama et al. and Tezuka does not teach the coating to have a non-uniform thickness which does not follow the tapered profile. However, McMahon discloses a guide wire with a coating of non-uniform thickness not following the tapered profile of the core to create a constant outer diameter (Fig. 1 ref. numbers 11, 13, 15 - sheath 15 is taken to be equivalent to a coating as Merriam-Webster dictionary defines a coat as 'a layer of one substance covering another' which is embodied by the sheath, and it does not follow the tapered profile of the elongated core, Col. 2 lines 45-46 - sheath is polymeric material). It would have been obvious to a person of ordinary skill in the art at the

time the invention was made to utilize a polymer coating with a non-uniform thickness in the guide wire of Murayama et al. because McMahon teaches this to create a constant outer diameter while still providing for areas of reduced surface contact along the length of the catheter.

With regard to claim 17, see member 17 (Fig. 7).

6. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Murayama et al. (US 2004/0039309 A1) in view of Tezuka (US 6,251,085 B1), McMahon (U.S. Patent 6,296,616), and Richardson et al. (WO 01/36034).

With regard to claim 31 Murayama et al. teach an intraluminal guide wire, comprising: an elongated core having a proximal core section and a distal core section including a taper transitioning to a distal end (Fig. 7); wherein an exterior surface of the distal core section includes randomized tactile surface contours as part of the distal core section itself (Fig. 7 members 17); and a flexible tubular member disposed over the distal core section (Fig. 7 member 4) wherein the proximal core section includes a high strength steel and the distal core section includes a nickel-titanium alloy (Fig. 7 sections 2 and 3, section 2 is made from a Nickel-Titanium alloy (Pg. 4 [0073]) and the proximal section 3 is made from a stainless steel (Pg. 4 [0071])); and the polymer coating includes a fluoropolymer (Col. 5 line 30).

Murayama et al. do not disclose a polymer coating having surface contours which follow the contours of the core. However, Tezuka teaches a guide wire with an uneven polymer coating and lubricious layer formed by following the outer surface contours of the guide wire which provides for a reduced contact surface to provide for increased slidability (Col. 2 line 64-Col. 3 line 5, claim 1). It would have been obvious to a person of ordinary skill in the art at the time the

invention was made to provide a coating over the surface contours in the device of Murayama et al. which follow the contours of the guide wire because Tezuka teaches this to allow for a reduced contact surface area and to provide slidability to the guide wire. A coating over the catheter would have a generally constant outer diameter as the surface contours provide for a portion of the catheter with a generally constant outer diameter. Murayama et al. and Tezuka does not teach the coating to have a non-uniform thickness which does not follow the tapered profile. However, McMahon discloses a guide wire with a coating of non-uniform thickness not following the tapered profile of the core to create a constant outer diameter (Fig. 1 ref. numbers 11, 13, 15 - sheath 15 is taken to be equivalent to a coating as Merriam-Webster dictionary defines a coat as 'a layer of one substance covering another' which is embodied by the sheath, and it does not follow the tapered profile of the elongated core, Col. 2 lines 45-46 - sheath is polymeric material). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to utilize a polymer coating with a non-uniform thickness in the guide wire of Murayama et al. because McMahon teaches this to create a constant outer diameter while still providing for areas of reduced surface contact along the length of the catheter.

Murayama et al. does not teach the surface contours to have a surface to peak amplitude in a range of about .0002 to .002 inches. However, McMahon teaches a guide wire with a plurality of contact and non-contact regions (Fig. 1 guide wire 10). These peaks have a height of about.01-.1mm which is approximately .0003 - .003in. (Col. 2 lines 59-61) and are used to reduce resistance (Col. 3 lines 1-14). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to create surface contours, in the guide wire of Murayama et al., with a surface-to-peak amplitude of about .0002 to .002 inches as McMahon

substantially discloses such a range to reduce the surface contact between the guide wire and the lumen through which it passes and is effective in reducing resistance. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Murayama et al. does not disclose the flexible tubular member disposed over the polymer coating. However, Richardson et al. discloses a coated guide wire with a flexible tubular member (Fig. 1 core member 11, proximal section 12, distal section 13, flexible member 14, coating 19). Richardson et al. teaches the coating can be applied anywhere along the core, thus, the flexible guide member would be over the coating (Pg. 20 lines 3-6) and additionally the coating can be applied over the flexible guide member, thus, the coating is disposed over the flexible guide member (Pg. 20 lines 3-6). This provides a lubricious coating to reduce friction. It would have been obvious to a person of ordinary skill in the art at the time the invention as made to dispose the flexible guide over the polymer coating in the device of Murayama et al. because Richardson et al. teaches such coatings to be lubricious and applied in any configuration to a guide wire and further it would have been obvious to a person of ordinary skill in the art at the time the invention was made to vary the placement of the coatings in order to achieve a desired amount of frictional resistance.

Response to Amendment

7. The amendments to the claims have been entered.

Response to Arguments

8. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Schmidt whose telephone number is (571) 270-3648. The examiner can normally be reached on Monday through Thursday 7:30 AM to 5:00 PM (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Emily Schmidt/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767